

Remarks

Status of the Claims

Claims 1-24 are pending in the application. Claims 1 and 23 have been amended, not in response to any rejections, but to correlate the language of these claims to the language of the specification. Specifically, the term “temporarily” has been replaced with the term “reversibly,” regarding transformation of the protection element. No new matter has been added by this amendment and support therefor can be found in paragraphs 0005 and 0013. Entry of the amendment is respectfully requested.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1, 3, 4, 8, 12-15, 17, 18, 20, 23 and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Daniel *et al.* (6,814,064), hereinafter “Daniel.” The Examiner contends that Daniel FIGS. 18B-18D disclose a distal protection apparatus as claimed. Applicant avers that Daniel fails to teach each and every element recited in claims 1 and 23. In particular, Daniel discloses no protection element comprising a self-expanded open configuration, as required by claims 1 and 23, in part. Applicant’s protection element has a mechanical memory in the shape of the open configuration, as described in paragraph 0008. Thus, the protection element will self-expand into the open configuration, absent any axial forces applied to transform it into its closed configuration:

This transformation can be reversed by removing the distal pressure applied by actuator 150 to proximal open apex 46, which will permit protection element 40 to expand itself back into the open configuration (paragraph 0013).

The cited protection device of Daniel is not self-expanding. Instead, the open configuration shown in FIGS. 18B and 18C of Daniel is formed by forcing together the ends of expandable member 262:

FIG. 18B illustrates device 250 in the deployed position in which expandable member 262 is radially expanded relative to the collapsed position shown in FIG. 18A. In order to deploy device 250, the outer tube 254 is moved distally with respect to inner wire 252 such that the distal ends 266 and 258 of wires 254 and 252 move longitudinally toward one another. Relative movement of ends 266 and 258 toward one another causes the mesh of expandable member 262 to buckle and fold radially outwardly (column 10, lines 56-64, emphasis supplied).

Therefore, in view of the above arguments, Daniel fails to teach each and every element of claims 1 and 23.

Claims 3, 4, 8, 12-15, 17, 18 and 20 depend from claim 1 and are patentable for at least the reasons discussed above regarding claim 1. Claim 24 depends from claim 23 and is patentable for at least the reasons discussed above regarding claim 23.

Claim Rejections under 35 U.S.C. § 103

Claims 2, 5-7, 9-11 and 16 stand rejected under 35 U.S.C. § 103 as being obvious in view of Daniel. Regarding claim 2, the Examiner contends that:

. . . although Daniel *et al.* do not disclose an inflated balloon, it is known in the art that an inflated balloon is couple to a distal protection device for treating a stenosis. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inflated balloon into the Daniel *et al.*'s distal protection apparatus in order to treat the stenosis (26, figure 1) as disclosed in Daniel *et al.* reference.

Applicant respectfully disagrees with the Examiner's characterization of the teachings of Daniel. In FIG. 12, Daniel discloses a balloon inflated within stenosis 26. In Daniel's FIG. 12, the balloon is displaced a distance away from filter device 18.

This rejection improperly uses Applicant's own claim 2 as a blueprint for selecting particular elements and combining them in the way the Applicant combined

them. As stated in *In re Gorman*, 933 F.2d 982:

It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.

See also *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, and *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, at 1551. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some suggestion or incentive supporting the combination. Nowhere does Daniel or another reference teach either the need or the utility of positioning a distal portion of an inflated balloon within a protection element, as required by claim 2, in part. Although Daniel's FIG. 12 shows concurrent use of an inflation balloon and a distal protection device, FIG. 12 does not illustrate any problem that could arise from positioning a distal protection apparatus at a spaced apart location from a treatment balloon. Thus, there is no incentive to make the claimed combination because the problem(s) addressed by Applicant, and the claimed solution(s) to these problems, is/are not found outside the pending application. Only the Applicant has identified the problem and a solution related to side branch protection.

Regarding claim 16, the Examiner contends that

. . . it would have been obvious matter of design choice to modify the Daniel *et al.* reference by having the distal open apex slidably attached to the distal end of a shaft and having a stop to prevent the distal advancement of the apex, since applicant has not disclosed by having the distal open apex slidably attached to the distal end of a shaft solve any problem or for any particular purpose and it appears that the protection element would perform equally well with the distal open end slidably attached and a stop or fixedly attached to the distal end of a shaft.

Applicant respectfully disagrees with this rejection and reiterates the above argument that obviousness cannot be established by combining the teachings of the prior art to produce

the claimed invention, absent some suggestion or incentive supporting the combination. Furthermore, Applicant indeed has explained a purpose for the distal open apex being slidably coupled to the shaft, as required by claim 16, in part:

In the embodiment shown, distal open apex 44 and proximal open apex 46 are both slidably coupled to shaft 35. Shaft 35 may first be introduced into the patient's vessel without protection element 40. Then, at the discretion of the clinician, protection element 40 may be slid onto the proximal end (not shown) of shaft 35 (paragraph 0012).

Paragraph 0012 also describes shaft 35 as being a "standard type steerable guidewire." Thus, the application teaches that a steerable guidewire can be located within a diseased vessel during a treatment procedure. If and when the clinician decides, in his or her discretion, that a distal protection element may be useful, then such an element may be slid onto the shaft of the guidewire. Such flexibility in the invention's utility to the clinician should not be disregarded.

Additionally, claims 2, 5-7, 9-11 and 16 depend from claim 1 and are patentable for at least the reasons discussed above regarding claim 1. In view of the above amendments and remarks, Applicant respectfully requests that the Examiner reconsider the outstanding rejections and that they be withdrawn.

Allowable Subject Matter

Applicant thanks the Examiner for the indicated allowability of claims 19, 21 and 22 if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant believes that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Dated this 16th day of July, 2004.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Catherine C. Maresh", written over a horizontal line.

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